K130869

510(k) Summary

MAY 3 0 2013

SYBRON DENTAL SPECIALTIES

Submitter:

Sybron Dental Specialties, Inc.
1717 West Collins Avenue
Orange, California 92867
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Wendy Garman - Contact Person

Date Summary Prepared: March 2013

- Trade name – *Take 1 Advanced*
- Common name – Dental Impression Material
- Classification name – Impression Material, per 21 CFR 872.3660
- Product Code - ELW

Devices for Which Substantial Equivalence is Claimed:

- Take 1, Kerr Corporation, K091613

Device Description

Take 1 Advanced is a complete system of vinylpolysiloxane impression materials composed of addition silicone chemistry where reaction between vinyl-terminated polydimethyl siloxane and poly-hydrogen siloxane catalyzed by platinum complex catalyst generates an optimum elastomeric material suitable for all crown and bridge, edentulous and implant impressions. The *Take 1 Advanced* system of materials is available in five viscosities, four delivery options, and in a range of set times. *Take 1 Advanced* has high elongation for easy mouth removal while its elastic recovery and tear strength provide accurate, detailed impressions time after time. The Wash viscosities are available in both Cartridge and Unidose syringe, a single use delivery system. The Tray viscosity is available in both Cartridge and Volume 5:1 delivery, for use in automated dynamic mixing machines. *Take 1 Advanced* offers three setting speeds: Regular Set, Fast Set, and Super Fast Set. Take 1 Advanced Putty is also available for Putty/Wash technique.

Indications for Use

Take 1 Advanced is a complete system of vinylpolysiloxane impression materials suitable for all crown and bridge, edentulous and implant impressions.

Summary of Technological Characteristics

Descriptive Information	*Take 1 Advanced*	Take 1 K091613
Company	**Kerr Corporation**	Kerr Corporation
Indications for Use	*Take 1 Advanced* is a complete system of vinylpolysiloxane impression materials suitable for all crown and bridge, edentulous and implant impressions.	*Take 1* is an addition-cure vinly polysiloxane dental impression material that is used for all crown and bridge, edentulous, orthodontic and implant impression techniques.
Description of Material	Vinly Polysiloxane	Vinly Polysiloxane
Mode of Use	1. *Take 1 Advanced* Light body/Regular body wash: A very hydrophilic impression material used in heavy/wash or putty/wash impression procedures and capable of capturing extraordinary subgingival details. It is used in crown and bridge and all high precision applications. 2. *Take 1 Advanced* Medium body: A medium viscosity monophase impression material with superior mechanical strength used in single step impression procedures such as mouth guards, night guards, orthodontic, and edentulous applications. 3. *Take 1 Advanced* Tray: A heavy body impression material combining strength, elasticity and dimensional stability to deliver the most accurate impressions. It is used in two-step heavy-wash applications such as for crown and bridge procedures.	1. Take 1 Light body/Regular body wash: A very hydrophilic impression material used in heavy/wash or putty/wash impression procedures and capable of capturing extraordinary subgingival details. It is used in crown and bridge and all high precision applications. 2. Take 1 Medium body: A medium viscosity monophase impression material with superior mechanical strength used in single step impression procedures such as mouth guards, night guards, orthodontic, and edentulous applications. 3. Take 1 Tray: A heavy body impression material combining strength, elasticity and dimensional stability to deliver the most accurate impressions. It is used in two-step heavy-wash applications such as for crown and bridge procedures.

Descriptive Information	*Take 1 Advanced*	Take 1 K091613
Principles of Operation	*Take 1 Advanced* is a dental impression that takes imprints of hard (teeth) and/or soft tissues. *Take 1 Advanced* captures a part or all of a person's dentition and surrounding structures of oral cavity. The dental impression forms an imprint (i.e. a 'negative' mold) of teeth and soft tissues, which can then be used to make a cast of the dentition. An impression is made by placing a viscous, thixotropic impression material into the mouth via a dental impression tray. The material, then sets to become an elastic solid, and, when removed from the mouth, provides a detailed and stable negative of teeth.	Take 1 is a dental impression that takes imprints of hard (teeth) and/or soft tissues. Take 1 captures a part or all of a person's dentition and surrounding structures of oral cavity. The dental impression forms an imprint (i.e. a 'negative' mold) of teeth and soft tissues, which can then be used to make a cast of the dentition. An impression is made by placing a viscous, thixotropic impression material into the mouth via a dental impression tray. The material, then sets to become an elastic solid, and, when removed from the mouth, provides a detailed and stable negative of teeth.
Shelf-Life	3 years	3 years

Non-Clinical Performance Data

Biocompatibility studies were completed which demonstrate that the material is safe for its intended use. Take 1 Advanced was tested through the following tests: Agar Diffusion Test- ISO Direct Contact, ISO Kligman Maximization Test and ISO Oral Irritation Test.

The 510(k) submission also includes data from bench testing used to evaluate performance characteristics of *Take 1 Advanced* as compared to the predicate device, Take 1 currently marketed by Kerr Corporation. The characteristics evaluated include Method of Manipulation, Work Time, Set Time, Strain in Compression, Deformation Recovery, Mixed Paste Consistency, Dimensional change, Hardness (Shore A), Compatibility with Die/Cast Material, Tensile Strength, Tensile Elongation, Tear Strength and Contact Angle.

Clinical Testing

Clinical testing has not been conducted on this product.

Conclusion

Based upon the biocompatibility tests and bench testing, the clinical performance of *Take 1 Advanced* is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 30, 2013

Ms. Wendy Garman
Director, Regulatory Affairs
Sybron Dental Specialties, Incorporated
1717 West Collins Avenue
Orange, California 92867

Re: K130869
Trade/Device Name: Take 1 Advanced
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: II
Product Code: ELW
Dated: March 28, 2013
Received: April 01, 2013

Dear Ms. Garman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Digitally signed by Mary S. Runner -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Mary S. Runner -S, 0.9.2342.19200300.100.1.1=1300087950
Date: 2013.05.30 13:12:16 -04'00'

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4

Indications for Use Statement

Indications for Use Statement

510(k) Number (if known): K130869

Device Name: ***Take 1 Advanced***

Indications For Use:

Take 1 Advanced is a complete system of vinylpolysiloxane impression materials suitable for all crown and bridge, edentulous and implant impressions.

Prescription Use __X__ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by Mary S. Runner -S
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Date: 2013.05.20 10:53:58 -04'00'

Susan Runner, DDS, MA

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K130869